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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,453	07/29/2003	Jack D. Keene	RBN-001DV	5725

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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,453	KEENE ET AL.	
	Examiner	Art Unit	
	Maria B Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 22-29* is/are rejected.

7)☒ Claim(s) *22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 December 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/29/04, 6/25/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to a preliminary amendment filed 7/29/03. Claims 30-33 have been cancelled. Claims 1-29 are pending in the application.

Information Disclosure Statement

Information disclosure statements filed 3/29/04 and 6/25/04 have been identified and the documents considered. The corresponding signed and initialed PTO Form 1449s have been mailed with this action. The documents listed as C16 in the IDS filed 3/29/04 and as C49 in the IDS filed 6/25/04 are International Search Reports which are not considered to be documents under 37 CFR 1.98. Therefore, the International Search Reports have been considered but have been crossed off the 1449 so that they will not appear on the face of any patent issuing form the instant application.

Drawings

The drawings are objected to because Figure 3 is oversized such that parts of the image of figure 3A are lost. Applicants should send a replacement drawing. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is vague and indefinite in that the metes and bounds of "identifying is carried out on a cDNA microarray" are unclear. It is unclear how the mRNA identification is carried out on a microarray. Furthermore, this claim depends from claim 23, which recites that the mRNA is identified by separating the mRNA and obtaining a cDNA. It is unclear which if these steps are to be carried on a cDNA microarray.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants claim a genus of RNA-associated proteins that associate with the mRNP complex with a Kd of about 10^6 to 10^9.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical

and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus. However, there is no actual reduction to practice or clear depiction of the claimed invention in detailed drawings. No structures of the claimed invention are disclosed. The structure of a species is disclosed as the specification discloses examples of RNA associated proteins that are well known in the art. The disclosed species are not representative of the genus because without knowing the Kd of its interaction with an mRNP complex, the invention will not operate as intended. Given the diversity of proteins claimed and the inability to determine which of these will also contain the essential element, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 8, 11-14, 17, 26 and 29 are rejected under 35 USC 102(b) as being anticipated by Allen et al (MCB, 1998, Vol 18, pages 6014-6022; see entire document).

Allen et al teach the isolation of mRNP complexes that comprise gRNA and mRNA associated with gBP21, an RNA binding protein (see e.g. page 6017, col 2, paragraph 3). Immunogenetic beads were generated comprising Dynabeads coated with goat anti-mouse IgGs coupled with purified MAbs (see e.g. page 6015, col 2, paragraph 5). Mitochondrial extract was incubated with the MAb specific beads and UV-cross-linking was performed after immunoprecipitation (see e.g. page 6016, col 1, paragraph 5) to partition the RNAs.

Claims 1, 2, 5-8, 12-15, 17, 25 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Antic et al (Genes and Development, 1999, Vol 12, page 449-461; see entire document).

Antic et al teach immunoprecipitation of mRNP complexes from cell lysates of human teratocarcinoma, hNT2 thus partitioning the mRNPs from the cell lysate (page 458, column 2, paragraph 2). hNT2 can differentiate into neurons (see e.g. page 450, col 2, paragraph) Cell lysates (biological sample) were combined with monoclonal antibody (ligand) such as anti-gene 10 (page 458, column 2, paragraph 2). The immunoprecipitated complex was separated by binding to protein A beads (page 458, column 2, paragraph 2). The Hel-N1 mRNPs complexes were immunoprecipitated by addition of protein A beads to the cell extract, the ligand (anti-g10) was attached to the solid support and lead to the isolation of the RNAs associated with the transfected Hel-N1 which was then identified by RT PCR (page 458, column 2, paragraph 2-4. NF-M was ultimately identified from these complexes.

Claims 1, 2, 8, 12-14, 17, 26 and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Reim et al (Experimental Cell Research, 1999, Vol 253, 573-586; see entire document).

Reim et al teach the partitioning of RNA molecules complexed to NonA protein. Kc cell extracts were combined with a plurality of antibodies such as NonA monoclonal antibody Bj6, S5, X4, P11 as well as ascites fluid and immunoprecipitated with protein A Sepharose (page 574,column 2, paragraph 3 and page 577, col 2, paragraph 2). Bound RNAs were extracted from the immune precipitated complex and prepared for RNA analysis (page 574, column 2 paragraph 4 and 5). RNA analysis was performed by slot blot analysis (page 581, column 2, last full paragraph).

Claims 1-9, 13-17, 23 and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Keene et al. US (5,773,246; see entire document).

Keene et al. teach immunoprecipitation of mRNP complexes from various tissues in Rat, which include organs, as well as from HeLa extracts, and Medullablastoma cell extracts (see e.g. col 23, line 44-52 and col 27, line 29-35). RNA isolated from Rat tissues was incubated with g10-Hel-N1 fusion protein prebound to protein-A beads using g-10 antibody, the products were purified and sequenced (see e.g. col 24 line 1-14). Extracts were incubated with rabbit anti-Hel N1 antibodies and immunoprecipitated with Staph A Sepharose beads (column 27, line 29-35). Bound RNAs were recovered by ethanol precipitation and a cDNA-subset library was prepared and the sequences determined by sequencing (column 28, line 1-20). Medullablastoma cells are neuralectodermal tumor-derived cells. The specification teaches that for easily degraded RNAs,

the RNA can be crosslinked to the mRNP complex (see e.g. col 20, line 37-47). Furthermore, Keene et al teach substitution of antibodies from sera of patients with cancer to immunoprecipitate Hel-N1 (see e.g. col 21, line 26-35).

Claims 1-6, 12-15, 17 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Buckanovich et al (Molecular and Cellular Biology. June 1997; see entire document).

Buckanovich et al. teach the recognition of RNA targets by the neuronal protein Nova-1. Adult mice brain nuclei were combined with affinity purified rabbit anti-Nova-1 antibodies and protein A Sepharose (page 3195,column 1, 3rd paragraph). Bound RNAs were extracted from the immune precipitated complex and prepared for RNA analysis (page 3195,column 1, 3rd paragraph). RNA analysis was performed by RT-PCR to assay glycine receptor 2, Nova-1, HuD, HelNI, clathrin, brain specific Na+ channel (page 3195, column 2, last full paragraph).

Claims 1, 2, 8, 10, 18, and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Takeda et al (J Immun, 1999, Vol 163, pages 6269-6274).

Takeda et al teach the isolation of an RNA-associated protein, Pa, and the identification of RNAs associated with it (see e.g. abstract). The mRNP complex was immunoprecipitated from HeLa cells using antibodies preincubated to protein A sepharose beads isolated from the sera of patients with autoimmune disorders (see e.g. page 6269, col 2, paragraphs 3-4).

Claims 1, 2, 8, 11-14, 17, 26 and 29 are rejected under 35 USC 102(b) as being anticipated by Allen et al (MCB, 1998, Vol 18, pages 6014-6022; see entire document).

Allen et al teach the isolation of mRNP complexes that comprise gRNA and mRNA associated with gBP21 (see e.g. page 6017, col 2, paragraph 3). Immunogenetic beads were generated that comprise beads coated with goat anti-mouse IgG couple with purified MAbs (see e.g. page 6015, col 2, paragraph 5). Mitochondrial extract was incubated with the MAb specific beads and UV-cross-linking was performed after immunoprecipitation (see e.g. page 6016, col 1, paragraph 5).

Conclusion

Claims 1-21 and 23-29 are rejected.

Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Zeta Adams, whose telephone number is (703) 308-01963291.

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Maria B Marvich, PhD
Examiner
Art Unit 1636

November 29, 2004

GERRY LEFFERS
PRIMARY EXAMINER